DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

APR - 9 1998

1152 '98 APR 15 P1:25

Robert A. Boutillier, Esq.
Mason, Taylor & Colicchio
104 Carnegie Center, Suite 201
Princeton, NJ 08540

Re: Docket No. 97N-0314/CP1

Dear Mr. Boutillier:

Pursuant to 21 CFR 10.30(e)(2), this letter informs you that the Food and Drug Administration (FDA) is still considering the issues raised in your citizen petition dated October 13, 1997, submitted on behalf of an unnamed pharmaceutical manufacturer. Your petition pertains to FDA's publication of a *Federal Register* notice affecting oral levothyroxine sodium drug products (62 FR 43535; August 14, 1997). You request that FDA rescind the following decisions contained or implicit in that notice: (1) that oral levothyroxine sodium drug products are "new drugs"; (2) that oral levothyroxine sodium drug products first marketed after August 14, 1997, are "new drugs"; and (3) that the "new drug" classification of oral levothyroxine sodium drug products is to apply immediately to new products entering the market after August 14, 1997, but products marketed on or before August 14, 1997, are to be "exempted from that classification" until August 14, 2000.

Work on the petition is still in progress. We will respond to your petition once we have reached a decision on your request.

Sincerely yours,

Ronald G. Chesemore
for Associate Commissioner
for Regulatory Affairs

97N-0314

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